

OCT 19 2004

K042740

510(k) Summary  
Pentax Confocal Laser System

**Submitter Information:** Pentax Medical Company  
102 Chestnut Ridge Road  
Montvale, New Jersey 07645-1856  
Tel: (201)-391-0932

**Name Of Device:**

|                      |   |
|----------------------|---|
| Trade Name:          | Pentax Confocal Laser System                            |
| Classification Name: | Endoscope and Accessories (78KOG) {876.1500} [Class II] |

**Predicated Device(s) Information:**

|                      |                  |         |
|----------------------|------------------|---------|
| Model, Description   | Manufacturer     | PMN#    |
| Zeiss Confocal Laser | Carl Zeiss, Inc. | K912581 |

**Device Description:**

The Pentax Confocal Laser System (software controlled device) is intended for use as a required accessory with Pentax video endoscope system that are equipped with confocal imaging module. The confocal laser system includes a laser light source, system computer, and display monitor. A video endoscope equipped with a confocal imaging module is connected to a conventional video endoscope system that will present the video endoscopic image. The endoscope is connected to the confocal system laser light source. The endoscope confocal imaging module contains an optical fiber that transmits laser light to, and receives return light from, the subject tissue. The confocal laser system contains a laser light source which produces visible laser light and contains signal detection circuitry to transmit/ receive the light signals through the endoscope confocal imaging module. The detected signal is sent to the system computer. The System Computer processes the confocal image information for display on the system monitor, controls the laser light source, and acts as an image storage device for still frame images.

**Intended Use:**

The Pentax confocal laser system is a required accessory for legally marketed video endoscopes equipped with a confocal laser imaging module. The system is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by the endoscope. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

**Comparison To Predicated Device(s):**

The submission for substantial equivalence included Pentax Confocal laser system literature including specifications, the identification of standard set components, and identification of optional accessories, comparison tables were provided to illustrate the comparisons to the predicated devices. The submission for substantial equivalence was not based on an assessment of clinical performance data.

**Prepared By:**

  
Paul Silva, Regulatory Affairs Coordinator

09-09-2004  
Date



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 19 2004

Pentax Medical Company  
c/o Mr. Tamas Borsai  
Division Manager, Medical Division, and  
Program Manager, Third Party Review Program  
TÜV Rheinland of North America  
12 Commerce Road  
Newtown, Connecticut 06470

Re: K042740  
Trade/Device Name: ISC-1000 Confocal Laser System  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: GCJ, KOG  
Dated: September 30, 2004  
Received: October 4, 2004

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

*for Miriam C. Provost*

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K042740  
Device Name: ISC-1000, Confocal Laser System

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

Prescription Use (Per 21 CFR 801.109)

510(k) Number K042740